Wyeth

May 7, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir or Madam:

Wyeth Pharmaceuticals, a Division of Wyeth, respectfully submits comments to the Food and Drug Administration (FDA) on the following two draft guidances, "Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms," and "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements." The availability of these draft guidances was announced in the *Federal Register*, Volume 69, Number 27, pages 6308-6309 (February 10, 2004).

Wyeth Pharmaceuticals is a major research-oriented pharmaceutical company with leading products in the areas of women's health care, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology and vaccines. Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

Wyeth has sponsored direct-to-consumer (DTC) advertising of prescription products, and believes that DTC advertising plays an important role in educating consumers about diseases and potential treatment options. Patients receive meaningful health information from DTC advertisements, including benefit and risk information about pharmaceutical products. Patients also receive direction to discuss presented information with their healthcare professional, thus enabling appropriate diagnosis and treatment. Wyeth acknowledges the intent of the Agency to facilitate communication of health-related information to consumers, and the submitted comments are offered for consideration.

Regarding the draft guidance, "Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms," Wyeth believes that the Agency does not have jurisdiction over non-branded help-seeking or disease awareness

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messages and this negates the ability of the Agency to issue the guidance. However, Wyeth suggests that the draft guidance be revised to present a focus on branded (product) advertisements, with Agency direction on elements of product advertisements that should and should not be used in order to avoid similarity with unbranded disease messages. With this perspective, Wyeth suggests that there is utility in having criteria established and communicated on the definition of close physical or temporal proximity of a disease awareness ad to a branded product ad. There should be solid, unbiased market research supporting any proposed criteria, and the criteria should cover both print and

broadcast ads. To facilitate generation of criteria, it is recommended that the FDA work with groups that collectively represent many pharmaceutical companies, such as PhRMA and BIO,[1] as well as non-industry groups that have expertise in conducting consumer market research surveys. Further, Wyeth recommends that any proposed criteria undergo public comment prior to implementation in a guidance.

Regarding the draft guidance, "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements," Wyeth concurs with the Agency that facilitating the communication of pharmaceutical product information to a consumer audience is important. However, throughout the draft guidance, the Agency uses the phrase "...does not intend to object..." when addressing brief summary alternatives. This phrase appears to intentionally dismiss the ability of a brief summary alternative to be considered in full compliance with applicable law and implementing regulations.[2] If the Agency considers a brief summary alternative acceptable, as presented in the draft guidance, any guidance that the Agency issues on brief summary alternatives should clearly state that the alternatives are "in compliance" with applicable law and implementing regulations. The explicit stating of compliance will assure the intended interpretation of the guidance for consumers, the industry and other interested parties.

The draft guidance specifically notes in its Introduction "This guidance does not focus on the presentation of risk information in the main body of the advertisement." Yet Section IV of the draft guidance, soliciting views of interested parties, focuses primarily on soliciting views on the presentation of risk information in the body of the ad. Inasmuch as the requirement for a brief summary is distinct from the requirement for presentation of risk information in an ad, Wyeth suggests deletion of Section IV from the final guidance.

Notwithstanding the aforementioned comment, Wyeth suggests that market research be conducted with consumers on the placement of risk information in an ad. To generate these data, it is recommended that the FDA work with groups that collectively represent

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[1] The Pharmaceutical Research Manufacturers of America and the Biotechnology Industry Organization, respectively.

[2] 21 U.S.C. 352(n); 21 CFR 202.1(e)(1); 21 CFR 202.1(e)(3)(iii).

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many pharmaceutical companies, such as PhRMA and BIO, as well as non-industry groups that have expertise in conducting consumer market research surveys. Further, Wyeth recommends that any proposal generated from this research undergo public comment prior to implementation in a guidance.

Wyeth appreciates the opportunity to submit comments on the aforementioned draft guidances. If there are any questions regarding this submission, please contact the undersigned.

Sincerely,

WYETH PHARMACEUTICALS, INC.

Diane Mitrione

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Worldwide Regulatory Affairs